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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,761	09/04/2003	Dennis Ausiello	17509-0065	6913

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EXAMINER	
MACNEILL, ELIZABETH	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/654,761	AUSIELLO ET AL.	
	Examiner	Art Unit	
	Elizabeth R. MacNeill	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-21,24,27,28,32 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-21,24,27,28,32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's arguments submitted 2 October 2006. All previous indications of allowability are withdrawn in light of the newly discovered references and rejection below.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-10,12-21,24,27,28,32, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over SANTINI (US 5,797,898) in view of UHLAND (US 2004/0121486), CHEIKH (US 5,660,846), Rubin (disclosed by applicant), HAGEMAN (US 6,011,011), and BARNARD (US 6,294,390).

Regarding claims 1, 12,24, Santini teaches a method and a device for controlled delivery of hormone to a patient in need thereof comprising: implanting a medical device (10) into the patient, the medical device comprising a substrate (14), a plurality of reservoirs (20a, 20b...) in the substrate, a release system (18) contained in each of the reservoirs, wherein the release system comprises a hormone, and a plurality of discrete reservoir caps (140) separating the release system from an environment outside of the reservoirs; disintegrating one or more of the reservoir caps to expose the release system to the environment, wherein the disintegration occurs by electrothermal

ablation; and releasing a pharmaceutically effective amount of the hormone from the reservoirs.

Regarding the disintegration of the caps by electrothermal ablation, Santini has disclosed that the following process dissolves his caps: "In the active timed release devices, the reservoir caps consist of thin films of conductive material patterned in the shape of anodes surrounded by cathodes. Any conductive material that can oxidize and dissolve in solution upon application of an electric potential can be used for the fabrication of the anodes and cathodes. Examples of such materials include metals such as copper, gold, silver, and zinc, and some polymers...The anode is defined as the electrode where oxidation occurs. The portion of the anode directly above the reservoir oxidizes and dissolves into solution upon the application of a potential between the cathode and anode. This exposes the release system to the surrounding fluids and results in the release of the molecules" (Col 5- Col 6, "Reservoir Caps").

Uhland discloses that "Electrothermal ablation reservoir opening devices, systems, and methods have been developed, for controlled reservoir opening. Generally, the device has a reservoir cap that is positioned over a reservoir opening to block the opening until release or exposure of the reservoir contents is desired and that functions as a heat generator. Electric current is used to provide local heating of the reservoir cap in an amount effective to rupture the reservoir cap, opening the reservoir. As used herein, the term "rupture" refers to an electrically-induced thermal shock that causes the reservoir cap structure to fracture, and/or to a loss of structural integrity of the reservoir cap due to a phase change, (e.g., melting or vaporization), either or both

of which are caused by the generation of heat within the reservoir cap as a result of electric current flowing through the reservoir cap. While not being bound to any theory, the heating causes the reservoir cap to degrade by melting (or vaporizing), thermal shock, and/or a mismatch in the coefficient of thermal expansion, thereby displacing the reservoir cap from over the reservoir and/or creating an aperture through the reservoir cap. This activation mechanism does not depend on a separate resistive heater element, for example, attached to an outer surface of a reservoir. **(This rupture process is analogous to the process by which a conventional simple electrical fuse heats and then disintegrates (e.g., burns up) upon passage of an excessive amount of electrical current through it.)**" (Emphasis added, P0029). Since the two processes (electrothermal ablation and electrochemical ablation) both require the same components (i.e. a metal film and electrical current) and have been discloses as analogous processes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Santini to include the rupture process of Uhland as an alternate means of exposing the reservoirs.

Regarding the delivery of parathyroid hormone, Santini has disclosed the release of a generic hormone from his device (Col 5, lines 12-18), but not specifically the parathyroid hormone. Cheikh discloses an implantable drug delivery device which can be used to deliver parathyroid hormone (Col 7 line 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the delivery device of Santini to deliver a parathyroid hormone since it is well known in the art to use an implantable drug delivery device to deliver parathyroid hormone.

Regarding claims 2-9,13,16 several of uses of parathyroid hormone in the treatment of bone loss are described in Rubin (as disclosed by applicant), and Santini discloses a release profile lasting from 3-13 months, as well as a pulsatile release.

Regarding claims 10 and 14,15, Santini discloses that more than one drug can be released from the reservoirs concurrently or with different release profiles.

Regarding claim 17, the number of reservoirs of Santini is only limited by the size of the device.

Regarding claims 18-21 and 36, Cheikh (Abstract) and Hageman (Col 3, line 28 – col 4, line 12) describe various means for releasing the parathyroid hormone with an excipient, the release system comprises parathyroid hormone in combination with a pharmaceutically acceptable excipient which promotes re-dissolution upon release.

Regarding claim 27, Santini discloses a biosensor on the device.

Regarding claim 28, all limitations except for the plasma calcium sensor have been disclosed. Barnard discloses a plasma calcium sensor which is design for long-term use in polymer membranes. The device of Barnard would be usable in the microchip of Santini, who has disclosed that biosensors could be used in conjunction with control means for releasing the parathyroid hormone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the sensor of Barnard with the microchip of Santini in order to provide a long lasting and highly sensitive means of measuring plasma calcium.

Regarding claim 32, the device is capable of vaginal administration of the parathyroid hormone.

Regarding claim 34, Santini discloses conducting leads to and from each reservoir cap (Fig 5)

Regarding claim 35, the release system comprises multiple layers of release system having different compositions (Fig 6a-6i).

Response to Arguments

3. Applicant's arguments with respect to claims 1-10,12-21,24,27,28,32, and 34-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

11/9/06

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER